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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. 09/294,980	Applicant(s) DOLLY ET AL.	
	Examiner Anne-Marie Baker	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6,9,11, and 13-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-6,9,11, and 13-24 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- |   |  |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____   |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other _____                                     |

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### **DETAILED ACTION**

The amendment filed October 2, 2000 (Paper No. 11) has been entered. Claims 7, 8, 10, and 12 have been cancelled.

Claims 1-6, 9, 11, and 13-24 are pending in the instant application.

### ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, drawn to methods for extending the effective time period tissue is paralyzed with a clostridial toxin comprising administering a binding protein agent/competitive inhibitor that prevents the regenerative activity of various neurotrophic factors, classified in class 514, subclass 2.
- II. Claims 1-6, drawn to methods for extending the effective time period tissue is paralyzed with a clostridial toxin comprising administering an antibody agent/competitive inhibitor that binds various neurotrophic factors, classified in class 424, subclass 130.1.
- III. Claims 1-6, 9, 11, and 13-24, drawn to methods for extending the effective time tissue is paralyzed with a clostridial toxin comprising administering agents that prevent the expression of various neurotrophic factor genes, including use of ribozymes, classified in class 514, subclass 44.

Claims 1-5 embrace the inventions of Groups I-III. Should any of Groups I-III be elected, Claims 1-5 will be examined only to the extent that they encompass the elected subject matter.

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Claim 6 embraces the inventions of Groups II and III. Should either of Groups II or III be elected, Claim 6 will be examined only to the extent that it encompasses the elected subject matter.

This application contains claims directed to the following patentably distinct species of the claimed invention:

- A. IGF I
- B. IGF II
- C. Ciliary neurotrophic factor
- D. NT-3
- E. NT-4
- F. Brain-derived neurotrophic factor
- G. Leukemia inhibitory factor
- H. Tenascin-C
- I. Ninturin
- J. Neural cell adhesion molecule
- K. Neural agrin

The different species of neurotrophic proteins as outlined in the species election requirement A-K represent distinct inventions because they are drawn to different proteins requiring different searches for each method of use. The proteins are not so related as to be considered obvious variants. Furthermore, there is nothing on the record to suggest that the proteins are obvious variants.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species associated with the elected invention, even though this requirement is traversed.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons:

Groups I-III are directed to methods of treating tissue with polypeptides, antibodies, and agents involved in gene therapy. Each of these methods require physically and functionally distinct elements. For example, the polypeptide agents used in the method of Group I interact with entirely different types of molecules that the nucleic acid molecules/ribozymes required in the method of Group III, and vice versa. The

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method of Group II also requires use of antibodies that are physically and functionally distinct from the polypeptides used in the method of Group I, or the nucleic acid agents used in the method of Group III, and vice versa. These inventions are, therefore, patentably distinct, since each method possesses its own unique materials and goals.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper. The search and examination of each group would constitute an undue burden on the examined, as each group requires a separate search and consideration of issues separately applicable to each group.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Baker whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached on (703) 305-6608. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-8724.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Anne-Marie Baker, Ph.D.

*Anne-Marie Baker*

ANNE-MARIE BAKER  
PATENT EXAMINER